

FORM T-1390 (Modified)
REV 5/98

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER

TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

197129US0PCT

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

09/623485

INTERNATIONAL APPLICATION NO.

PCT/JP99/00660

INTERNATIONAL FILING DATE

16 February 1999

PRIORITY DATE CLAIMED

30 March 1998 (earliest)

TITLE OF INVENTION

COVERING SHEET FOR SKIN AND HAIR

APPLICANT(S) FOR DO/EO/US

Nobuya SATO, et al.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 18 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
A **SECOND** or **SUBSEQUENT** preliminary amendment.
16. ☐ A substitute specification.
17. ☐ A change of power of attorney and/or address letter.
18. ☐ Certificate of Mailing by Express Mail
19. ☒ Other items or information:

Request for Consideration of Documents Cited in International Search Report

Notice of Priority

PCT/IB/304

PCT/IB/308

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

INTERNATIONAL APPLICATION NO.

ATTORNEY'S DOCKET NUMBER

09/623485

PCT/JP99/00660

197129US0PCT

20. The following fees are submitted:

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):

- ☒ Search Report has been prepared by the EPO or JPO **\$840.00**
- ☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) **\$670.00**
- ☐ No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) **\$760.00**
- ☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO **\$970.00**
- ☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) **\$96.00**

CALCULATIONS PTO USE ONLY**ENTER APPROPRIATE BASIC FEE AMOUNT =****\$840.00**Surcharge of **\$130.00** for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)).☐ 20☐ 30**\$0.00**

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	7 - 20 =	0	x \$18.00	\$0.00
Independent claims	2 - 3 =	0	x \$78.00	\$0.00
Multiple Dependent Claims (check if applicable). <input checked="" type="checkbox"/>				\$260.00
TOTAL OF ABOVE CALCULATIONS =				\$1,100.00
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). <input type="checkbox"/>				\$0.00
SUBTOTAL =				\$1,100.00
Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)). <input type="checkbox"/> 20 <input type="checkbox"/> 30				\$0.00
TOTAL NATIONAL FEE =				\$1,100.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). <input type="checkbox"/>				\$0.00
TOTAL FEES ENCLOSED =				\$1,100.00
			Amount to be refunded	\$
			charged	\$

☒ A check in the amount of **\$1,100.00** to cover the above fees is enclosed.☐ Please charge my Deposit Account No. _____ in the amount of _____ to cover the above fees.

A duplicate copy of this sheet is enclosed.

☐ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. _____ A duplicate copy of this sheet is enclosed.**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO:

NEUSTADT, P.C.

**22850**Surinder Sachar
Registration No. 34,423

SIGNATURE

Norman F. Oblon

NAME

24,618

REGISTRATION NUMBER

DATE

Sept. 17 2000

Description

Covering Sheet for Skin and Hair

Technical Field

The present invention relates to a sheet for covering the skin or hair, and more particularly to a sheet for covering the skin or hair which is capable of causing a useful medical ingredient to act effectively on the skin or hair while providing a comfortable sensation during use.

Background Art

In general, when any of variety of medical ingredients is applied to, for example, the skin or hair, such ingredient is directly applied thereto, or alternatively, paste containing such ingredients is applied in advance to a fabric substrate such as a non-woven fabric, and the paste-covered fabric is then applied to the skin or hair. For example, Japanese Patent Application Laid-Open (*kokai*) No. 62-286908 discloses a skin cosmetic agent for external use which comprises castor oil and beeswax formed into a jelly-like product. However, problems may arise with this presentation of the product; it is difficult to use, in that it may stain the clothing during use or remain on the skin after use. Japanese Patent Application Laid-Open (*kokai*) No. 55-92306 discloses a pack agent comprising an adhesive ingredient incorporating a cosmetic ingredient, the intended manner of

use being direct application to the skin. Similarly, Japanese Patent Application Laid-Open (kokai) Nos. 7-258060 and 9-295929 disclose a pack agent comprising an adhesive ingredient incorporating a whitening agent, and a pack agent comprising an adhesive ingredient incorporating an anti-wrinkle agent, respectively, which packs are assumed to be affixed to the skin. Japanese Patent Application Laid-Open (kokai) No. 2-36112 discloses a covering film for packing in which a heat-softened film is applied to the face or a part of the body, and then the film is cooled and hardened. In addition, Japanese Patent Application No. 9-194342 discloses an agent to prevent roughening of the skin comprising a polymer exhibiting high adhesion to skin. However, in the inventions disclosed in the above publications, a film (or sheet) must be affixed to the skin, and thus the film (or sheet) contains large amounts of a tacky ingredient. Therefore, such a film (or sheet) adheres firmly to the skin, and may induce an uncomfortable sensation or may cause problems when peeled off. In addition, when such a film (or sheet) is peeled off the skin, portions of the film (or sheet) may remain on the skin because of low film (or sheet) strength.

In view of the foregoing, an object of the present invention is to provide a novel composition for external use, which raises no problems associated with adhesion thereof to the skin and which can effectively supply a predetermined medical ingredient to a desired skin site and facilitate

action of the ingredient on the site.

Disclosure of the Invention

Conventionally, in order to cause a medical ingredient to act effectively on the skin, an adhesive layer is formed on a sheet bearing the ingredient, and the sheet is affixed to the skin. However, quite surprisingly, the present inventors have found that a thermoplastic resin sheet containing merely a medical ingredient in a predetermined amount is capable of causing the ingredient to act effectively on the skin or similar portions of the body through the effect of moistening the skin, etc. (hereinafter the effect will be referred to simply as "moistening effect") provided by the sheet, and that the problems occurring when the sheet is peeled off can be eliminated.

Accordingly, the present invention provides a sheet for covering the skin or hair comprising 100 parts by weight of a thermoplastic resin (A) and 0.01 to 200 parts by weight of a medical ingredient (B) acting on the skin or hair.

The present invention also provides a method for supplying the ingredient (B) to the skin or hair topically, characterized by covering the skin or hair with the above-described sheet.

Best Mode for Carrying Out the Invention

As used herein, the term "sheet" broadly refers to any material which can cover a site to which the material is

applied along the curved surface of the site. For example, such materials encompass films having a thickness of 100 μm or less, and sheet-like materials, including fiber-containing products such as non-woven fabric.

The thermoplastic resin (A) employed in the sheet of the present invention may be a commonly used thermoplastic resin. Examples of such resins include polyolefin resins such as polyethylene (e.g., low-density polyethylene, high-density polyethylene, linear low-density polyethylene, or very-low-density polyethylene), polypropylene, polybutene, and poly-4-methylpentene-1; polyolefin-modified resins or copolymers such as an ethylene-vinyl acetate copolymer, an ethylene-vinyl alcohol copolymer, an ethylene-methyl methacrylate copolymer, and an ethylene- α -olefin copolymer; polyamides such as 6-Nylon and 66-Nylon; polyesters such as polyethylene terephthalate and polybutylene terephthalate; polyvinyl chloride; polyvinylidene chloride and modified resins or copolymers thereof; polystyrene; polyvinyl acetate; polyacrylonitrile; polycarbonate; and polyacrylate.

In order to impart flexibility to a sheet and ensure that its properties allow it to conform itself to the skin or hair, it is preferable to employ an ethylene- α -olefin copolymer having a density of less than 0.920 g/cm^3 (e.g., a copolymer produced by use of a cyclopentadienyl catalyst); polypropylene having a flexural elastic modulus of $5,000 \text{ CN/cm}^2$ or less (as measured in accordance with ASTM-D790); and a polymer which is mixed with ethylene-propylene rubber

during polymerization (e.g., Catalloy, product of Montell).

In addition, a polymer known as thermoplastic elastomer (TPE) may be employed in the present invention. Examples of TPEs include styrene TPE comprising polystyrene serving as a hard segment, and polybutadiene, polyisoprene, or poethylene-polybutylene serving as a soft segment; olefin TPE comprising polypropylene serving as a hard segment and EPDM or EPM serving as a soft segment; urethane TPE comprising polyurethane serving as a hard segment and polyether or polyester serving as a soft segment; ester TPE comprising polyester serving as a hard segment and polyether or polyester serving as a soft segment; PVC-TPE; butyl rubber graft polyethylene comprising polyethylene and butyl rubber; 1,2-polybutadiene comprising 1,2-syndiotactic polybutadiene and amorphous polybutadiene; trans-1,4-polyisoprene comprising trans-1,4-polyisoprene and amorphous polyisoprene; an ionomer comprising metal carboxylate cluster and amorphous polyethylene; and natural rubber TPE comprising polypropylene and natural rubber.

When such a thermoplastic elastomer is incorporated into the sheet, the sheet acquires flexibility and has those properties which allow it to conform closely to the skin or hair. In order to obtain such effects, a thermoplastic elastomer is incorporated, into 100 parts by weight of the resin (A), in an amount of 1-95 parts by weight, preferably 10-80 parts by weight, more preferably 20-60 parts by weight.

Examples of the medical ingredient (B) which may be

employed in the present invention include a moisturizer, a whitening agent, a UV absorber, a slimming agent, a circulation promoter, an astringent, an anti-inflammatory agent, a wrinkle-formation preventive and ameliorating agent, a cooling agent, a warming agent, a hair remover, a hair growing agent, a hair-growth regulating agent, and a hair nourishing agent.

Specific examples are:

(1) natural fats and oils, and hydrogenated oils or glyceride derivatives which are obtained through hydrogenation of the natural fats and oils, such as beef tallow, milk fat, lard, sardine oil, mackerel oil, tuna oil, shark liver oil, linseed oil, safflower oil, sunflower oil, soybean oil, corn oil, peanut oil, sesame oil, rapeseed oil, olive oil, palm oil, palm-kernel oil, coconut oil, and castor oil;

(2) middle and higher fatty acids, such as butyric acid, caproic acid, caprylic acid, capric acid, lauric acid, myristic acid, palmitic acid, palmitoleic acid, stearic acid, oleic acid, linoleic acid, linolenic acid, moroctic acid, arachidic acid, eicosenoic acid, arachidonic acid, eicosapentaenoic acid, behenic acid, erucic acid, docosapentaenoic acid, docosahexaenoic acid, lignoceric acid, selacholeic acid, and isostearic acid;

(3) ester derivatives formed of the aforementioned higher fatty acids (2) and glycerin or polyglycerins, such as monoesters and diesters;

(4) higher alcohols which are obtained through reduction of the aforementioned higher fatty acids (2), such as lauryl alcohol, cetyl alcohol, stearyl alcohol, and oleyl alcohol, and ester derivatives of the alcohols;

(5) hydrocarbons such as liquid paraffin, paraffin, vaseline, paraffin micro-crystalline wax, ceresine, pristane, and squalane;

(6) waxes such as carnauba wax, beeswax, and lanolin;

(7) ceramides and analogue substances thereof, cholesteryl esters, vitamins (e.g., vitamin A, vitamin B, vitamin C, vitamin D, vitamin E, and derivatives of the vitamins), polyoxypropylene fatty acid esters, and cholesterol;

(8) crude drugs, Chinese herbal drugs, herbs, perfumes, and silicones;

(9) UV screen, UV absorption, or UV protection agents (e.g., benzophenone compounds, p-aminobenzoic acid compounds, methoxycinnamic acid compounds, and salicylic acids); titanium oxide, zirconium oxide, iron oxide, and micro particle treatment substances thereof; and surface treatment or composite treatment substances of silicone or zirconia-alumina.

One or more substances of these may be employed in the present invention. Of these medical ingredients (B), oily substances of (1) through (6) are preferably employed as the medical ingredient (B). If necessary, substances of (1) through (6), and (7) or weak alkaline inorganic compounds

such as magnesium oxide and calcium hydroxide may further be incorporated into the sheet in appropriate amounts.

The amount of medical ingredient (B) is 0.01-200 parts by weight, preferably 0.1-100 parts by weight, more preferably 1-50 parts by weight, on the basis of 100 parts by weight of the resin (A). When the amount of the ingredient (B) is less than 0.01 parts by weight, the sheet does not exhibit the desired properties, whereas when the amount is in excess of 200 parts by weight, stable high-yield production of the sheet cannot be achieved.

In the sheet of the present invention, medical ingredient (B) is dispersed in resin (A) so that a required amount of the ingredient (B) can be supplied to the covered site when a target site is covered with the sheet. Thus, the sheet does not require an adhesive layer that is essential to conventional patches.

The sheet of the present invention can be produced through, for example, the following process.

Firstly, the resin (A) is mixed with the medical ingredient (B). The resin (A) may be heated and melted, and then mixed with the ingredient (B). Alternatively, the resin (A) may be dissolved in a predetermined solvent, and then mixed with the ingredient (B).

In production, the sheet may be shaped by use of a T die, an inflation apparatus, or a calender. The sheet may be produced by cutting a film or sheet comprising a single layer or two or more layers into a predetermined size or shape.

The resin (A) and the medical ingredient (B) may be kneaded at a temperature at which the resin (A) is melted or a higher temperature through a non-woven fabric production process, such as a spun bond process or melt blowing, to thereby produce a non-woven fabric.

The sheet may be shaped after the resin (A) is mixed with the medical ingredient (B) at high pressure by use of a solvent which is compatible with the resin (A) at high pressure and which is separated from the resin at low pressure. The mixing process is usually employed to produce flash spinning fiber. The sheet produced through the process takes the form of a fibrous aggregation, and is gas-permeable and waterproof

The sheet of the present invention which is produced through the above process may be easily applied to a portion of the body by winding a bandage or a similar material around the site.

When the surface of the sheet of the present invention is made flat and smooth, the sheet *per se* of the present invention exhibits a strong adhesive force between sheets. Therefore, the sheet does not stick to the skin or clothing, the body is tightly wrapped and sealed with the sheet, the evaporation of moisture from the skin surface can be suppressed, and even when there is only a small amount of the medical ingredient (B) contained in the sheet, it can be effectively absorbed percutaneously through the moistening effect.

When the sheet is applied as described above, the cohesive force between the sheets is 2,000 cN/4 cm² or more, preferably 3,000 cN/4 cm² or more, more preferably 5,000 cN/4 cm² or more. The cohesive force between the sheets is obtained as follows: two sheets having a length of 75 mm and a width of 20 mm are made to overlap each other at 20°C such that the area of the overlapped region is 4 cm²; a load was applied onto the overlapped portion under a rubber roller of 400 g (10 cm/sec; 2 reciprocations); and a shear peel strength of the sheets is obtained by use of Tensilon (product of Orientec).

In order to cause the sheet to have a cohesive force which is equal to or higher than that of the resin (A), an oily ingredient may be incorporated into the sheet as the medical ingredient (B) or another ingredient. Varying the type or amount of the oily ingredient can control the cohesive force.

For example, when natural fats and oils, hydrogenated oils or glyceride derivatives which are obtained through hydrogenation of the natural fats and oils, higher fatty acids, higher alcohols or ester derivatives thereof, ester derivatives formed of higher fatty acids and glycerin or polyglycerins, such as monoesters and diesters, or hydrocarbons are added to the resin (A), the resin is softened and a strong cohesive force is generated between the sheets. The thus-generated cohesive force brings the sheets to tightly contact to each other, without permitting the

sheets to stick to or adhere to the skin or clothing. The cohesive force between the sheets may be increased through reduction in the density of the resin, in addition to the use of the aforementioned oily ingredient.

When the sheet is applied to an uneven part of the body or where the body flexes, the sheet may be held in place by means of any fixation method, in addition to the adhesion force of the sheet. For example, supporters, gloves, socks, and stockings may be employed to thereby bring the sheet into effective contact with the intended site of the body.

When the sheet is employed in such a manner, the sheet preferably fits closely and flexibly against the skin. In view of the foregoing, the sheet of the present invention preferably has a thickness of 5-200 μm , more preferably 5-100 μm .

When the sheet of the present invention is in the form of non-woven fabric, the flexibility of the sheet may be represented better by basis weight than thickness. The basis weight of the sheet is preferably 5-200 g/m², more preferably 5-100 g/m². When the sheet has a basis weight falling within such ranges, body-contour conformity (tight contact) of the sheet to the body is enhanced, and the flexibility thereof is improved. When another non-woven fabric or sheet is laminated onto the sheet of the present invention or when a composite sheet is formed of the sheet of the present invention, the basis weight of the laminated sheet or the composite sheet is the sum of the basis weight of the sheet

of the present invention and that of the additional sheet(s). In this case, the sum of the basis weights may exceed the above optimal range given for the basis weight of the sheet of the present invention.

In order to enhance flexibility of the sheet produced from resin (A), it is preferable that the aforementioned thermoplastic elastomer, oily ingredient, or flexible polyolefin resin be added to the sheet. When flexibility of the sheet is represented by percentage of stretching, the sheet of the present invention is capable of being stretched by 50% or more. In order to obtain excellent conformity of the sheet to the body, the modulus when the sheet is stretched by 50% is 1-2,000 cN/10 mm, preferably 10-1,000 cN/10 mm, and more preferably 10-500 cN/10 mm.

Because the sheet of the present invention is used to cover the skin or hair, it is better if the sheet does not adhere to the skin or hair to protect the skin or hair from any damage. As used herein, the phrase "the sheet does not adhere to the skin" refers to the case in which the sheet substantially does not adhere to the skin, i.e., peeling off the sheet covering the skin does not require additional force. However, when the sheet is applied to a portion of the body having an uneven contour or to only a part of the body, a tackifier may be incorporated into the sheet so long as the intended effect of the present invention is not impeded. Examples of tackifiers which may be employed in the present invention include natural resins such as rosin and dammar,

polyterpene resins, and aliphatic hydrocarbon resins. These tackifiers are described in "Kobunshi Kako, special issue 8, Nenchaku" (republished by Kobunshi Kankokai, on July 15, 1976, page 105, Table 1). Of these tackifiers, one or more species may be employed in the sheet of the present invention. The amount of a tackifier which is incorporated into the sheet must be determined such that the tackifier does not cause any damage to the skin. In view of the foregoing, the amount of a tackifier which is incorporated into the polyolefin resin (A) (100 parts by weight) is 99 parts by weight or less, preferably 75 parts by weight or less, more preferably 50 parts by weight or less.

The sheet of the present invention comprises the medical ingredient (B) on the inside and on the surface of the sheet prepared from resin (A). Therefore, in order to prevent the ingredient (B)—which is present on the sheet surface and opposed against the skin—from adhering to another part of the body or to the clothing, any barrier material may be laminated onto the sheet so as to form a multi-layer structure. For example, a thermoplastic resin or a thin film made from an inorganic compound not containing the ingredient (B) may be employed as a back-coating, or a non-woven fabric may be laminated onto the sheet. When another non-woven fabric or sheet is laminated onto the sheet of the resin (A) or a composite sheet is formed of the sheet of the resin (A), the overall thickness of the laminated sheet or the composite sheet may exceed the above preferable

range for the thickness of the sheet of the present invention.

The sheet of the present invention may be embossed during production in order to control the sensation produced on the skin. By whatever means the sheet is produced to increase its bulkiness, the effect of the present invention is not impeded so long as the thickness of the sheet basically falls within 5-200 μm as described above.

The sheet of the present invention can be produced in such a way that it possesses an appropriate moisture permeability to impart both a moistening sensation and a refreshing sensation to the skin. Specifically, the moisture permeability of the sheet may be controlled by adding any of the following polymers to the sheet: ethylene copolymers having a polar group, such as an ethylene-vinyl acetate copolymer of relatively low moisture permeability; and polyurethane elastomers or polyester elastomers which may have high moisture permeability. These polymers may be employed singly or in combination. Incidentally, micropores may be formed in the sheet. No particular limitation is imposed on the method for creating micropores in the sheet, and micropores are formed by means of, for example, laser processing or discharge processing as disclosed in Japanese Patent Application Laid-Open (*kokai*) No. 4-279321. Alternatively, inorganic filler can be added to the sheet and the pores are then formed through stretching. A different method again is where pores can be formed through melting using heated pins.

The aforementioned sheet (non-woven fabric) produced through flash spinning, melt blowing, or spun-bond processing is permeable to the air. In order to control the air permeability of such a sheet, the sheet may be treated by pressing it with a roller.

Examples

Example 1

Castor oil serving as a medical ingredient (B) (5 parts by weight) was added to linear low-density polyethylene (Ultzex 15100, product of Mitsui Chemicals, Inc.) (80 parts by weight) and very low density polyethylene (DFDB9042, product of Nippon Unicar Co., Ltd.) (20 parts by weight), serving as a resin (A). The resultant mixture was melted at 170°C and kneaded, and then shaped at 200°C by use of a T die, to thereby produce the sheet of the present invention having a thickness of 30 μm .

Examples 2 through 15

The sheets of the present invention were produced in a manner similar to that of Example 1 under conditions shown in Tables 1 through 4.

Comparative Example 1

A sheet having a thickness of 20 μm was produced by use of linear low-density polyethylene (Ultzex 15100, product of Mitsui Chemicals, Inc.) serving as a resin (A).

Test Example 1

The five persons enrolled in the test were covered or

patched with the sheets of Examples 1 through 15 and Comparative Example 1 on the backs of their hands, heels, knees, and necks for 30 minutes. The sensations caused by the sheets (tight contact, conformity, moistness after use, and peelability) were organoleptically evaluated in accordance with the below-described criteria. The results are shown in Tables 1 through 4.

<Evaluation criteria>

(1) Cohesive force

Cohesive force between the sheets were measured as described above.

(2) Conformity

Conformity was determined by the number of persons who reported "the sheet did not slip off the site to which the sheet had been applied, and the sheet conformed to movement of the joint."

Four or more: good

Three or less: poor

(3) Moistness after use

Moistness after use was determined by the number of persons who reported "the site to which the sheet had been applied became moistened after use, or a reduction in the number of wrinkles was observed."

Four or more: good

Three or less: poor

(4) Peelability

Peelability was determined by the number of persons who

reported "there was no irritation to the skin, and no debris of epidermis or hair was observed on the surface of the sheet after use."

Four or more: good

Three or less: poor

Table 1

(unit: parts by weight)

Resin/Medical ingredient/Production conditions/Properties	Product name	Maker	Examples				
			1	2	3	4	5
Low-density polyethylene	Mirason 11P	#1		20	10		
Linear low-density polyethylene	Ultrex 15100	#1	80				
very low-density polyethylene	DFDB 9042	#2	20				
Ethylene- α -olefin copolymer	Affinity EG8200	#3		80			
Ethylene-vinyl acetate copolymer	Evaflex P2807	#4			45		
Ethylene-methacrylate	Acryft CM4013	#5			45		
Polypropylene	KS357P	#6				80	
Polypropylene	PF-814	#6				20	60
Polypropylene	F569D	#7					40
Polybutene	Tafmer BL2481	#1					
Castor oil (natural product)			5	10	30		
Olive oil (natural product)							
Soybean oil (natural product)							
Corn oil (natural product)						30	
Coconut oil (natural product)							50
Kneading temperature (°C)			170	160	170	200	200
Shaping method				T die			Inflation
Shaping temperature (°C)			200	200	200	220	220
Sheet pressure (μm)			30	10	20	25	25
Cohesive force (cN/4cm ²)			6000	5000	5500	3000	3500
Conformity			Good	Good	Good	Good	Good
Moistness after use			Good	Good	Good	Good	Good
Peelability			Good	Good	Good	Good	Good

#1 Mitsui Chemical, Inc., #2 Nippon Unicar Co., Ltd., #3 Dow Chemical Co.,

#4 Mitsui-Du Pont Co., #5 Sumitomo Chemical Co., Ltd., #6 Montor S.p.A, #7 Grand Polymer

Table 2

(Incorporation unit: parts by weight)

Resin/Medical ingredient/Conditions for production/Properties	Product name	Maker	Examples					
			6	7	8	9	10	
Low-density polyethylene	Mirason 11P	#1				10		80
Linear low-density polyethylene	Ultrez 15100	#1	80					
Linear low-density polyethylene	Ultrez 2080	#1		80		50		
Very low-density polyethylene	DFDB9042	#2				40		20
Ethylene- α -olefin copolymer	Affinity EG8200	#3						
Ethylene- α -olefin copolymer	Tafmer S4030	#1			40			
Ethylene-ethyl acrylate-maleic anhydride copolymer	Bondine TX8030	#5		20				
Polypropylene	F569D	#7			60			
Styrene elastomer	Kraton G1657	#8	20					0.1
Olive oil (natural product)								
Corn oil (natural product)			35	15	25	15		
Rapeseed oil (natural product)				0.1	1	1		
Vitamin E (natural product)								
Ceramide (synthetic product)								
Kneading temperature (°C)			180	180	200	180		180
Shaping method			T die					
Shaping temperature (°C)			220	200	220	200		200
Sheet pressure (μ m)			20	25	75	25		200
Cohesive force (cN/4cm ²)			6500	7000	4000	5000		3000
Conformity			Good	Good	Good	Good		Good
Moistness after use			Good	Good	Good	Good		Good
Peelability			Good	Good	Good	Good		Good

#1 Mitsui Chemical, Inc., #2 Nippon Unicar Co., Ltd., #3 Dow Chemical Co.,

#5 Sumitomo Chemical Co., Ltd., #7 Grand Polymer, #8 Shell Kagaku K.K.

(Incorporation unit: parts by weight)

Table 3

Resin/Medical ingredient/Conditions for production/Properties	Product name	Maker	11	12	13
			T die		
Low-density polyethylene Linear low-density polyethylene Ethylene- α -olefin copolymer Ethylene-vinyl acetate copolymer Urethane elastomer Ester elastomer	Mirason llP SP2520	#1	60	60	100
	Affinity EG8150	#3	40	40	
	Evaflex P2807	#4			
	Toyobo Urethane E3080AK	#5			
	Pelprene P-30B05	#5			
Olive oil (natural product)			3	10	30
Soybean oil (natural product)					
Rapeseed oil (natural product)					
Ceramide (synthetic product)			180	180	170
Kneading temperature (°C)					
Shaping method					
Shaping temperature (°C)			200	200	200
Sheet pressure (μ m)			100	35	20
Cohesive force (cN/4cm ²)			8000	7500	7500
Conformity			Good	Good	Good
Moistness after use			Good	Good	Good
Peelability			Good	Good	Good

#1 Mitsui Chemical, Inc., #3 Dow Chemical Co., #4 Mitsui-Du Pont Co.,
 #5 Toyobo Co., Ltd.

Table 4

(Incorporation unit: parts by weight)

Resin/Medical ingredient/Conditions for production/Properties	Product name	Maker	Examples		Comp. Ex.
			14	15	
Linear low-density polyethylene Ethylene- α -olefin copolymer Ethylene-vinyl acetate copolymer Urethane elastomer Ester elastomer	Mirason 11P	#1			100
	SP2520	#1			
	Affinity EG8150	#3			
	Evaflex P2807	#4			
	Toyobo Urethane E3080AK	#5	10	100	
Rapeseed oil (natural product) Ceramide (synthetic product) Kneading temperature (°C)	Pelprene P-30B05	#5	10	10	
			1	1	
			180	180	-
Shaping method			T die		
Shaping temperature (°C)			200	200	200
Sheet pressure (μ m)			30	25	20
Cohesive force (cN/4cm ²)			6000	6000	0
Conformity			Good	Good	Poor
Moistness after use			Good	Good	Poor
Peelability			Good	Good	Good

#1 Mitsui Chemical, Inc., #3 Dow Chemical Co., #4 Mitsui-Du Pont Co.,

#5 Toyobo Co., Ltd.

As is apparent from Tables 1 through 4, the sheet of the present invention provides excellent tight contact and conformity to the skin, and also provides excellent moistness to the skin due to the effect of a medical ingredient contained in the sheet. In addition, the sheet causes no irritation and, upon peeling, little damage to the skin.

Test Example 2

The arms of the two persons enrolled in the test were placed in an atmosphere (temperature: 25°C, humidity: 50%) for 30 minutes, and then the water content of the horny layers of the arms was measured in reference to the conductivity of skin surface. The conductivity was measured by use of a high-frequency resistance meter (model: SKICON-200, product of Hamamatsu). In a separate experiment, the procedure of Example 1 was repeated, except that olive oil (10 parts by weight) was employed as a medical ingredient, to thereby obtain a film. Subsequently, the right arm of each person enrolled in the test was covered with the thus-obtained film for 15 minutes, and then the film was removed from the arm. Fifteen minutes after removal of the film, the water content of the horny layers of the right arm was measured again. As a control, the left arm of each person was covered with the film of Comparative Example 1, and the water content of the horny layers of the arm was measured in a manner similar to that described above. The results are shown in Table 5.

Table 5

		Water content of horny layers (μ S)	
		Tested person A	Tested person B
Right Arm	Before covering	5.2	8.3
	After covering (Sheet of Present Invention)	23.0	44.2
Left Arm	Before covering	7.2	8.7
	After covering (Control)	7.7	20.3

As is apparent from Table 5, the sheet of the present invention facilitates the medical ingredient contained in the sheet to exhibit its effect (in this case, the moistening effect of olive oil) through covering with the sheet.

Industrial Applicability

The sheet of the present invention exhibits the following effects through wrapping, in addition to the above-described effects. Namely, the surface of the skin is sealed with the sheet through wrapping, and thus a medical ingredient contained in the sheet rapidly permeates the skin and the ingredient is effectively absorbed percutaneously through the moistening effect. In addition, the skin is protected from external irritations through wrapping with the sheet. For example, the skin can be prevented from chapping which is caused by scratching an itchy portion of the skin.

Moreover, since the sheet of the present invention has a simple structure, the sheet can be easily shaped and can be produced at an improved production efficiency.

Claims:

1. A sheet for covering the skin or hair comprising 100 parts by weight of a thermoplastic resin (A) and 0.01 to 200 parts by weight of a medical ingredient (B) acting on the skin or hair.
2. A sheet according to claim 1, which comprises no adhesive layer other than the sheet itself containing the ingredients (A) and (B).
3. A sheet according to claim 1 or 2, wherein the ingredient (A) is a polyolefin resin.
4. A sheet according to claim 1 or 2, wherein the ingredient (B) is selected from the group consisting of a moisturizer, a whitening agent, a UV absorber, a slimming agent, a circulation promoter, an astringent, an anti-inflammatory agent, a wrinkle-formation preventive and ameliorating agent, a cooling agent, a warming agent, a hair remover, a hair growing agent, a hair-growth regulating agent, and a hair nourishing agent.
5. A method for supplying a medical ingredient acting on the skin or hair (B) to the skin or hair topically, characterized by covering the skin or hair with a sheet comprising 100 parts by weight of a thermoplastic resin (A) and 0.01 to 200 parts by weight of the medical ingredient (B).

ABSTRACT

The present invention is directed to a sheet for covering the skin or hair containing 100 parts by weight of a thermoplastic resin (A) and 0.01-200 parts by weight of a medical ingredient (B) acting on the skin or hair, and to a method for supplying the ingredient (B) to the skin or hair topically by use of the sheet.

The sheet causes a useful medical ingredient to act effectively on a site of the skin or hair to which the sheet is applied, while providing a comfortable sensation during use.

Declaration and Power of Attorney For Patent Application

特許出願宣言書及び委任状

Japanese Language Declaration

日本語宣言書

下記の氏名の発明者として、私は以下の通り宣言します。

As a below named inventor, I hereby declare that:

私の住所、私書箱、国籍は下記の私の氏名の後に記載された通りです。

My residence, post office address and citizenship are as stated next to my name.

下記の名称の発明に関して請求範囲に記載され、特許出願している発明内容について、私が最初かつ唯一の発明者（下記の氏名が一つの場合）もしくは最初かつ共同発明者（下記の名称が複数の場合）であると信じています。

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled.

皮膚又は毛髪用被覆シート

Covering Sheet for Skin and Hair

上記発明の明細書は、

☐ 本書に添付されています。

☒ 1999年2月16日に提出され、米国出願番号または特許協定条約国際出願番号を PCT/JP99/00660 とし、

(該当する場合) _____ に訂正されました。

the specification of which

☐ is attached hereto.

☒ was filed on February 16, 1999

as United States Application Number or

PCT International Application Number

PCT/JP99/00660 and was amended on

_____ (if applicable).

私は、特許請求範囲を含む上記訂正後の明細書を検討し、内容を理解していることをここに表明します。

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

私は、連邦規則法典第37編第1条56項に定義されるとおり、特許資格の有無について重要な情報を開示する義務があることを認めます。

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

Japanese Language Declaration

(日本語宣言書)

私は、米国法典第35編119条 (a) - (d) 項又は365条 (b) 項に基づき下記の、米国以外の国の少なくとも一カ国を指定している特許協力条約365 (a) 項に基づく国際出願、又は外国での特許出願もしくは発明者証の出願についての外国優先権をここに主張するとともに、優先権を主張している、本出願の前に出願された特許または発明者証の外国出願を以下に、枠内をマークすることで、示しています。

Prior Foreign Application(s)

外国での先行出願

10-83580

(Number)

(番号)

10-160227

(Number)

(番号)

Japan

(Country)

(国名)

Japan

(Country)

(国名)

I hereby claim foreign priority under Title 35, United States Code, Section 119 (a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or Section 365(a) of any PCT International application which designated at least one country other than the United States, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or PCT International application having a filing date before that of the application on which priority is claimed.

Priority Claimed

優先権主張

☒ Yes ☐ No

はい いいえ

30/03/1998

(Day/Month/Year Filed)

(出願年月日)

09/06/1998

(Day/Month/Year Filed)

(出願年月日)

☒ Yes ☐ No

はい いいえ

私は、第35編米国法典119条 (e) 項に基づいて下記の米国特許出願規定に記載された権利をここに主張いたします。

(Application No.)

(出願番号)

(Filing Date)

(出願日)

私は、下記の米国法典第35編120条に基づいて下記の米国特許出願に記載された権利、又は米国を指定している特許協力条約365条 (c) に基づく権利をここに主張します。また、本出願の各請求範囲の内容が米国法典第35編112条第1項又は特許協力条約で規定された方法で先行する米国特許出願に開示されていない限り、その先行米国出願書提出日以降で本出願書の日本国内または特許協力条約国際提出日までの期間中に入手された、連邦規則法典第37編1条56項で定義された特許資格の有無に関する重要な情報について開示義務があることを認識しています。

(Application No.)

(出願番号)

(Filing Date)

(出願日)

(Application No.)

(出願番号)

(Filing Date)

(出願日)

私は、私自信の知識に基づいて本宣言書中で私が行なう表明が真実であり、かつ私の入手した情報と私の信じるところに基づく表明が全て真実であると信じていること、さらに故意になされた虚偽の表明及びそれと同等の行為は米国法典第18編1001条に基づき、罰金または拘禁、もしくはその両方より処罰されること、そしてそのような故意による虚偽の声明を行えば、出願した、又は既に許可された特許の有効性が失われることを認識し、よってここに上記のごとく宣誓を致します。

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below.

(Application No.)

(出願番号)

(Filing Date)

(出願日)

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s), or Section 365(c) of any PCT International application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code Section 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of application.

(Status: Patented, Pending, Abandoned)

(現況：特許許可済、係属中、放棄済)

(Status: Patented, Pending, Abandoned)

(現況：特許許可済、係属中、放棄済)

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Japanese Language Declaration
(日本語宣言書)

委任状：私は下記の発明者として、本出願に関する一切の手続きを米特許商標局に対して遂行する弁理士または代理人として、下記の者を指名いたします。
(弁理士、または代理人の指名及び登録番号を明記のこと)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith: (*list name and registration number*)

Norman F. Oblon, Reg. No. 24,618; Marvin J. Spivak, Reg. No. 24,913; C. Irvin McClelland, Reg. No. 21,124; Gregory J. Maier, Reg. No. 25,599; Arthur I. Neustadt, Reg. No. 24,854; Richard D. Kelly, Reg. No. 27,757; James D. Hamilton, Reg. No. 28,421; Eckhard H. Kuesters, Reg. No. 28,870; Robert T. Pous, Reg. No. 29,099; Charles L. Gholz, Reg. No. 26,395; William E. Beaumont, Reg. No. 30,998; Jean-Paul Lavalleye, Reg. No. 31,451; Stephen G. Baxter, Reg. No. 32,884; Richard L. Treanor, Reg. No. 36,379; Steven P. Wehrhouch, Reg. No. 32,829; John T. Goolkasian, Reg. No. 26,142; Richard L. Chirrin, Reg. No. 34,305; Steven E. Lipman, Reg. No. 30,011; Carl E. Schlier, Reg. No. 34,426; James J. Kultascki, Reg. No. 34,648; Richard A. Neifeld, Reg. No. 35,299; J. Derek Mason, Reg. No. 35,270; Surinder Sachar, Reg. No. 34,423; Christina M. Gadiano, Reg. No. 37,628; Jeffrey B. McIntyre, Reg. No. 36,867; William T. Enos, Reg. No. 33,128; Michael E. McCabe, Jr., Reg. No. 37,182; Bradley D. Lytle, Reg. No. 40,073; and Michael R. Casey, Reg. No. 40,294, with full powers of substitution and revocation.

書類送付先

Send Correspondence to:

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
FOURTH FLOOR
1755 JEFFERSON DAVIS HIGHWAY
ARLINGTON, VIRGINIA 22202 U.S.A.

直接電話連絡先：(名前及び電話番号)

Direct Telephone Calls to: (name and telephone number)

(703) 413-3000

単独発明者または第一の共同発明者の氏名 佐藤 信也 1-CC	Full name of sole or first joint inventor <u>Nobuya SATO</u>
発明者の署名 <u>Nobuya Sato</u> 日付 Sept. 1, 2000	Inventor's signature Date
住所 321-3497 日本国栃木県芳賀郡市貝町赤羽 2606 花王株式会社研究所内	Residence C/O KAO CORPORATION RESEARCH LABORATORIES 2606 Akabane, Ichikaimachi, Haga-gun, TOCHIGI 321-3497 JAPAN
国籍 日本国	Citizenship JAPANESE
郵便の宛先 住所に同じ	Post Office Address SAME AS ABOVE
第二の共同発明者の氏名 山内 通秀 2-CC	Full name of second joint inventor, if any <u>Michihide YAMAUCHI</u>
第二の共同発明者の署名 <u>Michihide Yamauchi</u> 日付 Sept. 1, 2000	Second joint Inventor's signature Date
住所 321-3497 日本国栃木県芳賀郡市貝町赤羽 2606 花王株式会社研究所内	Residence C/O KAO CORPORATION RESEARCH LABORATORIES 2606 Akabane, Ichikaimachi, Haga-gun, TOCHIGI 321-3497 JAPAN
国籍 日本国	Citizenship JAPANESE
郵便の宛先 住所に同じ	Post Office Address SAME AS ABOVE

(第三以降の共同発明者についても同様に記載し、署名すること)

(Supply similar information and signature for third and subsequent joint inventors.)